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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,144	03/29/2004	Emmanuel Cyrille Pascal Briend	674525-2011	3079

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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,144	BRIEND ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-69, drawn to a method for modulating an immune response by administering a modulator of Notch intracellular protease activity, classified in for example class 435, subclass 7.21.

II. Claims 70 and 71, drawn to a modulator and a composition comprising the modulator, classified in for example class 514, subclass 885.

III. Claims 72-74 and 78-79, drawn to a method for producing of lymphocytes, classified in for example class 435, subclass 2.

IV. Claims 75-77 and 80-81, drawn to a method for treating a subject having a disease of abnormal lymphocyte activity by administering cells produced by Group III, classified in for example class 424, subclass 93.1.

V. Claim 83, drawn to a method of vaccinating a subject against a tumor by administering a tumor antigen, classified in for example class 435, subclass 130.1.

VI. Claims 84-88, drawn to a method for identifying modulators of Notch intracellular domain protease activity, classified in for example class 435, subclass 7.21.

VII. Claims 89-96, drawn to a composition comprising a modulator of Notch intracellular domain protease activity and an antigen determinant, classified in for example class 424, subclass 9.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II, Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the modulators/compositions in the Groups I and V can be practiced using alternative nucleic acids, antisense oligonucleotides, siRNA, antibodies or peptides; and the products as claimed in the Groups II and VII can be used alternatively in a method of treating other diseases related to Notch intracellular signaling pathway, such as neurodegenerative diseases or diseases related to neural development. Thus, Inventions I and II, Inventions V and VII are patentably distinct.

3. Inventions II and VII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the antigenic determinant and adjuvants in the Group VII are not required in the Group II. Thus, Inventions II and VII are patentably distinct.

4. Inventions I, II, Inventions V, VII and Inventions III, IV, VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP § 806.04, MPEP § 808.01). In this instant case, first, the procedures, materials and equipments used in the method of identifying a modulator (Group VI) are very different from those in the methods of treating diseases (Groups I, IV and V) and the method of producing lymphocytes. For example, in the Groups I, IV and V, the technology, materials and patients are not required for screening a modulators and preparing lymphocytes. In addition, the outcomes and effects in the method of treating patients with modulators are very different those in the method of treatment with lymphocytes or vaccine. The procedures, materials and the equipments involved are very different. The patient populations may be different within these different treatment methods. The health and physiological conditions are very distinct. For example, the mental status, behavior, symptoms and the medication conditions as well as the etiology and pathology are very different. Thus, Inventions I, II, Inventions V, VII and Inventions III, IV, VI are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VII to which the claims will be restricted, even

though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Election of Species

7. This application contains claims directed to the following patentably distinct species of the claimed inventions I-VII:

i. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the agonist selected from A) polypeptides/fragments/peptides, B) nucleic aids, C) compounds, or D) antibodies recited in claims 4 and 8 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

ii. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the condition of administration selected from A) ex vivo or B) in vivo recited in claims 36, 37, 65and 66 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

iii. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the effect of modulator selected from A) up-regulates/enhancer or B) down-regulates/inhibitor recited in claims 9,11, 13, 14,

22, 23, 25, 26, 28, 29, 31, 32, 34, 35, 40, 47, 48, 51, 52, 58, 59, 60, 61 and 69 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

iv. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for T-cell selected from A) effector, B) helper, C) cytotoxic,or D) regulatory recited in claims 20-35 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

v. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for polypeptide selected from A) Notch ligands, B) Noggin, C) Chordin, D) Follistatin, E) Xnr3, F) FGF, G) Toll-like receptor, H) cytokine, I) BMP, J) BMP receptor, or K) activin recited in claims 13 and 14 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

vi. If Group I is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for cytokine selected from A) IL-10, B) IL-5, C) IL-4, D) IL-2, E) TNF-a, F) IFN-r, or G) IL-13 recited in claims 46-61 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

vii. If Group III or Group IV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for cells selected from A) APC, or B) T cell recited in claims 72-74, 78, 79, and 81 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 72, 74, 78, 79 and 81 are generic.

8. The species listed above are patentably distinct for the following reasons: These species are distinct because they are different molecules, effects, conditions, and cells. Each molecule differs in structure and function as they are composed of divergent amino acids, and the use for each molecule is different. They are also differentially able to bind to other molecules or mediate other biological functions. Therefore, these different molecules constitute very divergent subject matters. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive. In addition, the cell components and biological characteristics are very different in different cell types. Consequently the responses of these different cell types to different biomolecules are also distinct. Further, the molecular mechanisms contributed to the action of each molecule are very different and so are the effects. Moreover, the outcomes and effects in the method of ex vivo are very different from

those in the condition of in vivo. The patient populations are not required in the method of ex vivo. Thus, these species are patently distinct.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a

single group from designated Groups I-VII and a single species from groups i-vii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

15. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30

AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
March 13, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER